## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUN 28 2011

***Halifax Biomedical Inc.'s Tantalum Bead Set***

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| **Submitter Name:** | BioVera, LLC. |
| **Submitter Address:** | 3 Elizabeth Place, Lake Hopatcong, NJ 07849 |
| **Contact Person:** | Robert A Poggie, PhD |
| **Phone Number:** | (973) 738-6097 |
| **Fax Number:** | (973) 663-4462 |
| **Date Prepared:** | June 20, 2011 |
| **Manufacturer Name:** | Halifax Biomedical, Inc. |
| **Manufacturer Address:** | 11493 Route 19, Mabou, Nova Scotia, B0E 1X0, CANADA |
| **Contact Name:** | Chad Munro, P.Eng, MASc (Biomed.) |
| **Title:** | President and CEO |
| **Device Trade Name:** | The Tantalum Bead Set |
| **Device Common Name:** | Radiographic Marker |
| **Classification Name:** | Marker, Radiographic, Implantable |
| **Classification Code:** | NEU – Class II |
| **Classification Panel:** | General & Plastic Surgery |
| **Regulation Number:** | 21 CFR § 878.4300 |

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**Device Description:** The Tantalum Bead Set consists of 1mm spherical x-ray markers made of commercially pure, unalloyed tantalum. The tantalum beads are used as radio opaque markers that are implanted in bone or soft tissue. The tantalum beads are used to measure changes in position of prostheses and anatomical structures with the aid of x-ray images. The tantalum beads are implanted with a manual instrument. The tantalum beads are provided in a cartridge (set of 16 beads, "The tantalum Bead Set") that is inserted into the manual instrument. The instrument inserts one Tantalum bead via manual activation by the surgeon. The Tantalum Bead Set is provided in the sterile condition; sterility is achieved by means of gamma radiation with a sterility assurance of $10^{-6}$ SAL.

**Device Description continued...**

The predicate device, also called the Tantalum Bead Set, was supplied non-sterile. Sterilization was performed via steam prior to use in surgery. The 1mm tantalum markers are identical in every respect; the only change is gamma irradiation for sterility.

The Tantalum Bead Set, both predicate and subject devices, includes a cartridge that holds the 16 tantalum markers and interfaces with the class I instrument for implanting the tantalum markers. The cartridge for both the predicate and subject devices does not come in contact with the patient's tissues or fluids. The predicate cartridge was made with PEEK, while the subject cartridge is made with PPSU (Radel).

**Indications for Use:**

Tantalum bead implants are used as radio-opaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an x-ray system. Implant surgery associated with the use of radiographic markers may include total joint replacement procedures, soft tissue repair, and bone fracture fixation procedures.

**Laboratory Testing & Evaluation:**

The following tests were performed to confirm substantial equivalence of the subject device.

- Functional testing of the Tantalum Bead Set showed no evidence of debris or abrasion during the functioning of the instrument.
- Sterility validation per ISO 11137-1 and -2:2006 for the gamma irradiation sterilization of the Tantalum Bead Set. The validation showed the Tantalum Bead Set to achieve a SAL $10^{-6}$.
- Package integrity and shelf-life testing per ISTA 2A:2008 and ASTM standards F1980, F2096, & F1140.

**Conclusions:**

The results of the non-clinical testing showed: (1) 5-year shelf life for the sterilized and packaged Tantalum Bead Set, (2) $10^{-6}$ SAL via gamma irradiation of the Tantalum Bead Set. These results indicate that supplying the Tantalum Bead Set as sterile is as safe and effective, and will perform as well as the predicate device, the Tantalum Bead Set that was supplied non-sterile.

**Substantial Equivalence:**

The Tantalum Bead Set, Sterile is substantially equivalent to the identified predicate device, the Tantalum Bead Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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JUN 28 2011

Re: K103417
Trade/Device Name: The Tantalum Bead Set
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: June 20, 2011
Received: June 21, 2011

Dear Dr. Poggie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number:** 103417

**Device Name:** The Tantalum Bead Set

**Indications For Use:**

Tantalum bead implants are used as radio-opaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an x-ray system. Implant surgery associated with the use of radiographic markers may include total joint replacement procedures, soft tissue repair and bone fracture fixation procedures.

| Prescription Use (Part 21 CFR 801 Subpart D) | | AND/OR... | Over-The-Counter Use (21 CFR 801 Subpart C) | |
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| | X | | | |

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K103417

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)